September 25, 2013

pSivida Corp. Reports Fourth Quarter and Fiscal Year 2013 Results

WATERTOWN, Mass.--(BUSINESS WIRE)-- pSivida Corp. (NASDAQ: PSDV)(ASX: PVA), a leader in developing sustained release, drug delivery products for treatment of back-of-the-eye diseases, today announced financial results for its fourth quarter and fiscal year ended June 30, 2013.

"In fiscal 2013, we made a major step forward in our transition to a Specialty Pharma company with the start of the first of two planned pivotal Phase III clinical trials for our own lead development product, the micro-insert Medidur™ for posterior uveitis," said Dr. Paul Ashton, President and CEO of pSivida. "Uveitis is the third leading cause of blindness in the U.S. Because Medidur uses the same micro-insert as ILUVIEN® , our partnered product for diabetic macular edema (DME), the FDA has agreed that we can use much of the data, including clinical safety data, from the completed ILUVIEN Phase III trials to support an application for Medidur for posterior uveitis. This should shorten and simplify the regulatory process.

"We also received encouraging interim results from a Phase I/II investigator-sponsored study of Medidur for posterior uveitis. While early, they were consistent with our hypothesis that Medidur should treat posterior uveitis with an efficacy profile comparable to Retisert®, our FDA-approved implant for uveitis that delivers the same drug as Medidur, and a side effect profile superior to Retisert and comparable to ILUVIEN for DME."

ILUVIEN for chronic DME considered insufficiently responsive to available therapies, licensed to Alimera Sciences, is now being sold in Germany and the U.K., and Alimera has reported its plans for a commercial launch in France in early 2014. ILUVIEN for DME has also received marketing authorization in Austria, Portugal and Spain, and has been recommended for marketing authorization in Italy. In the U.S., the FDA is reviewing the New Drug Application for ILUVIEN for DME resubmitted earlier this year and has set a Prescription Drug User Fee Act (PDUFA) target date of October 17, 2013. Approval in the U.S. would entitle pSivida to a $25 million milestone payment from Alimera. pSivida is also entitled to 20% of net profits, as defined, from sales of ILUVIEN by Alimera on a country-by-country basis.

Alimera has continued to advance pricing and reimbursement for ILUVIEN for DME in the EU. In the U.K., where ILUVIEN is currently available only to privately insured and private pay patients, the U.K.'s National Institute for Health and Care Excellence (NICE) is considering the recommendation of its appraisal committee to change published guidance to allow ILUVIEN for the treatment of pseudophakic patients (those who have already undergone cataract replacement surgery) with chronic DME. If adopted by NICE, the U.K.'s National Health Service is expected to fund ILUVIEN treatment for this large subset of the chronic DME population. In Germany, Alimera was permitted to launch ILUVIEN for DME without price restriction and is in the process of securing agreements for reimbursement with German statutory insurance funds to avoid individual patient requests for reimbursement. In France, ILUVIEN for DME received a favorable opinion for the reimbursement and hospital listing by the French National Health Insurance of ILUVIEN, and 100% of its cost will be reimbursed under a program for severe chronic disease, such as diabetes.

"Pre-clinical testing of Tethadur™, our second key technology platform, continues to progress well," continued Dr. Ashton. "Tethadur offers the potential to deliver peptides, proteins and antibodies on a sustained basis, which would be very effective in the development of Biosimilars and Biobetters. There is currently no sustained ophthalmic delivery technology available for these biologics, which typically require frequent injection into the eye.

"The use of Tethadur in certain ophthalmic applications is being evaluated under a funded evaluation agreement with a leading global biopharmaceutical company. Two other major pharmaceutical companies are evaluating our technology platforms in other ophthalmic applications under funded agreements."

Revenues for the fiscal year ended June 30, 2013 totaled $2.1 million compared to $3.5 million for the prior fiscal year. The decline in collaborative research and development revenues principally reflected $1.1 million of non-recurring revenue recognition in fiscal 2012 from termination of a license agreement. Royalty income for fiscal 2013 reflected a small increase over the prior fiscal year in royalties from sales of Retisert by Bausch & Lomb.

Net loss for fiscal 2013 was $11.9 million, or $0.52 per share, compared to a net loss of $24.8 million, or $1.19 per share, for the prior fiscal year. Fiscal 2012 results included a $14.8 million impairment charge for pSivida's finite-lived intangible assets arising from the November 2011 complete response letter for ILUVIEN for DME and the resulting significant decrease in

pSivida's market capitalization.

Revenues for the fiscal 2013 fourth quarter were $492,000 compared to $699,000 for the fourth quarter last year. The Company reported a net loss of $3.9 million, or $0.17 per share, for the fourth quarter ended June 30, 2013, compared to a net loss of $2.3 million, or $0.11 per share, for the fourth quarter of the prior year. The higher net loss in the fourth quarter of fiscal 2013 primarily reflected costs associated with the initiation of the Phase III uveitis clinical trial and accruals for two years of incentive compensation, as both fiscal 2012 and 2013 bonuses were earned based on fiscal 2013 performance conditions.

At June 30, 2013, cash, cash equivalents and marketable securities totaled $10.3 million. In July 2013, the Company completed an underwritten public offering of common shares for gross proceeds of approximately $10.8 million.

Today's Conference Call Reminder

pSivida Corp. will host a live webcast and conference call today, September 25, 2013, at 4:30 pm ET. The conference call may be accessed by dialing (877) 312-7507 from the U.S. and Canada, or (631) 813-4828 from international locations. The conference can also be accessed on the pSivida Corp. website at www.psivida.com. A replay of the call will be available approximately two hours following the end of the call through October 2, 2013. The replay may be accessed by dialing (855) 859-2056 within the U.S. and Canada or (404) 537-3406 from international locations, Conference ID number 68809431.

About the Clinical Trials/Studies

pSivida has initiated the first of two planned pivotal Phase III trials of Medidur for the treatment of posterior uveitis. These trials are expected to enroll a total of approximately 300 patients. The primary end point is the recurrence of uveitis within 12 months. pSivida will be permitted to reference much of the data, including the clinical safety data, from the clinical trials for ILUVIEN for DME conducted by Alimera.

The investigator-sponsored Phase I/II study of Medidur for posterior uveitis is a three-year study that will evaluate the safety and efficacy of Medidur in up to 12 patients with posterior uveitis. Interim results were measured on the twelve month anniversary of the start of enrollment. Through this period, none of the eyes receiving Medidur experienced a recurrence of uveitis and inflammation was reduced in all of these eyes. In contrast, all (untreated) control eyes had either a recurrence of uveitis or a worsening of inflammation. Furthermore, at the last follow-up visit reported in interim results, best corrected visual acuity (on the Early Treatment Diabetic Retinopathy Study eye chart) improved by an average of more than nine letters in treated eyes while untreated eyes declined by an average of one letter. Interim data showed that Medidur was well tolerated, and the observed safety profile was consistent with the short-term safety profile reported in clinical studies of ILUVIEN in DME eyes. Only one eye receiving Medidur measured an increase in intraocular pressure above the normal range.

About pSivida Corp.

pSivida Corp., headquartered in Watertown, MA, develops tiny, sustained release, drug delivery products designed to deliver drugs at a controlled and steady rate for months or years. pSivida is currently focused on treatment of chronic diseases of the back of the eye utilizing its core technology systems, Durasert™ and BioSilicon™, including Tethadur™. The injectable, sustained release micro-insert ILUVIEN® for the treatment of chronic Diabetic Macular Edema (DME) considered insufficiently responsive to available therapies, licensed to Alimera Sciences, Inc., is marketed in the U.K. and Germany and has also received marketing authorization in Austria, France, Portugal, and Spain and is awaiting authorization in Italy. Alimera resubmitted the New Drug Application for ILUVIEN for DME to the U.S. Food and Drug Administration and received a PDUFA date of October 17, 2013. pSivida has instituted the first of two planned pivotal Phase III clinical trials for Medidur™ for the treatment of posterior uveitis, a chronic back-of-the-eye disease, using the same micro-insert as ILUVIEN for DME. An investigator-sponsored clinical trial is ongoing for an injectable, bioerodible micro-insert to treat glaucoma and ocular hypertension, a product candidate on which Pfizer Inc. has an option. pSivida's FDA-approved Retisert®, licensed to Bausch & Lomb Incorporated, provides long-term, sustained drug delivery to treat posterior uveitis.

SAFE HARBOR STATEMENTS UNDER THE PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995: Various statements made in this release are forward-looking, and are inherently subject to risks, uncertainties and potentially inaccurate assumptions. All statements that address activities, events or developments that we intend, expect or believe may occur in the future are forward-looking statements. The following are some of the factors that could cause actual results to differ materially from the anticipated results or other expectations expressed, anticipated or implied in our forward-looking statements: uncertainties with respect to: the ability to finance, complete and achieve a successful outcome for Phase III trials for, and file and achieve marketing approvals for, Medidur for posterior uveitis, including efficacy, side effects and risk/benefit profile, as well as uncertainty as to the ultimate results of the investigator-sponsored trial for Medidur for posterior uveitis; Alimera's ability to finance, achieve additional marketing approvals, successfully complete pricing and reimbursement discussions for, commercialize and achieve market acceptance of, and generate revenues to pSivida from, ILUVIEN for DME in the EU; Alimera's ability to obtain regulatory approval for, and if approved, to finance, successfully commercialize and achieve market acceptance of, and generate revenues to pSivida from, ILUVIEN for DME in the U.S.; initiation, financing and success of Latanoprost Product Phase II trials and exercise by Pfizer of its option; ability to utilize Tethadur and BioSilicon to develop

product candidates and products and potential related collaborations; initiation and completion of clinical trials and obtaining regulatory approval of product candidates; continued sales of Retisert; adverse side effects; ability to attain profitability; ability to obtain additional capital; further impairment of intangible assets; fluctuations in operating results; decline in royalty income; ability to, and to find partners to, develop and market products; termination of license agreements; competition and other developments affecting sales of products; market acceptance; protection of intellectual property and avoiding intellectual property infringement; retention of key personnel; product liability; consolidation in the pharmaceutical and biotechnology industries; compliance with environmental laws; manufacturing risks; risks and costs of international business operations; credit and financial market conditions; legislative or regulatory changes; volatility of stock price; possible dilution; possible influence by Pfizer; absence of dividends; and other factors described in our filings with the SEC. Given these uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements. Our forward-looking statements speak only as of the dates on which they are made. We do not undertake any obligation to publicly update or revise our forward-looking statements even if experience or future changes makes it clear that any projected results expressed or implied in such statements will not be realized.

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The President's Blog: http://www.thechairmansblog.com/paul-ashton

For more information on pSivida, visit www.psivida.com.

PSIVIDA CORP. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)
(In thousands except per share amounts)

	Three Months Ended June 30,		Year Ended June 30,	
	2013	**2012**	**2013**	**2012**
Revenues:				
Collaborative research and development	$ 177	$ 257	$ 780	$ 2,080
Royalty income	315	442	1,363	1,446
Total revenues	492	699	2,143	3,526
Operating expenses:				
Research and development	2,320	1,410	7,005	7,039
General and administrative	2,153	1,599	7,169	6,868
Impairment of intangible assets	-	-	-	14,830
Total operating expenses	4,473	3,009	14,174	28,737
Operating loss	(3,981)	(2,310)	(12,031)	(25,211)
Other income (expense):				
Change in fair value of derivatives	-	-	-	170

Interest income	2	8	16	38
Other expense, net	-	-	(2)	(1)
Total other income	2	8	14	207
Loss before income taxes	(3,979)	(2,302)	(12,017)	(25,004)
Income tax benefit	32	40	117	169
Net loss	$ (3,947)	$ (2,262)	$(11,900)	$(24,835)
Net loss per share:				
Basic and diluted	$ (0.17)	$ (0.11)	$ (0.52)	$ (1.19)
Weighted average common shares outstanding:				
Basic and diluted	23,297	20,803	23,044	20,791

PSIVIDA CORP. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)
(In thousands)

	June 30, 2013	June 30, 2012
Assets		
Current assets:		
Cash, cash equivalents and marketable securities	$ 10,273	$ 14,571
Other current assets	2,191	1,388
Total current assets	12,464	15,959
Intangible assets, net	3,430	4,226
Other assets	355	412
Total assets	$ 16,249	$ 20,597
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 2,565	$ 1,002
Deferred revenue	738	2,176
Derivative liabilities	-	-
Total current liabilities	3,303	3,178
Deferred revenue	5,246	3,783
Deferred tax liabilities	-	-
Total liabilities	8,549	6,961
Stockholders' equity:		

Capital	270,438	264,452
Accumulated deficit	(263,658)	(251,758)
Accumulated other comprehensive income	920	942
Total stockholders' equity	7,700	13,636
Total liabilities and stockholders' equity	$ 16,249	$ 20,597

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